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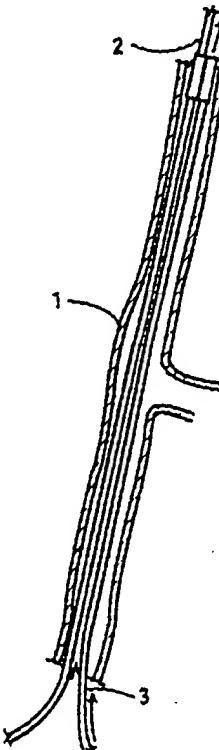
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(54) Title: GUIDING DEVICE AND METHOD FOR INSERTING AND ADVANCING CATHETERS AND GIDEWIRES INTO A VESSEL OF A PATIENT IN ENDOVASCULAR TREATMENTS

(57) Abstract

A guiding device and method for inserting and advancing more than one catheter and/or guidewire through the vascular tree of a patient in endovascular treatments, particularly through tortuous blood vessels, the guiding device comprising an open or close guiding channel provided at a distal end of the catheter or guidewire, whereby the catheter or guidewire may be easily advanced through the vessel over a previously installed guidewire.



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**GUIDING DEVICE AND METHOD FOR INSERTING AND ADVANCING
CATHETERS AND GUIDEWIRES INTO A VESSEL OF A PATIENT IN
ENDOVASCULAR TREATMENTS**

BACKGROUND OF THE INVENTION

5 1. Field of the Invention.

The present invention relates to the field of endovascular treatments and, more particularly relates to a guiding device for helping in inserting and advancing catheters and/or guidewires into blood vessels of a patient during endovascular treatments, the invention also being related to a method for inserting and advancing such catheters and/or 10 guidewires.

15 2. Description of the Prior Art.

Angioplasty and other endovascular techniques are well known and broadly utilized medical processes consisting of inserting catheters and/or guidewires into the vascular tree of a patient with the purpose of reaching a remote blood vessel site having a lesion. The 20 catheters and guidewires must be carefully maneuvered and steered through the patient's vessels until reaching the site of the lesion. A premise and basic requisite in the handling of these techniques is to provide an accurate and non-traumatic positioning of the catheters and guidewires in the desired vessel site and in the advancing of the wires and catheters along the vascular tree.

Under predetermined circumstances two guidewires need to be inserted into a blood vessel under treatment in order to have one of the guidewires located in the desired site. When two guidewires are used, the exchange of the guidewires is performed by advancing a catheter over a first guidewire that had been previously inserted and located into the vessel. Once the catheter has reached the desired area the first guidewire is 25 removed and a second guidewire is advanced through a lumen of the catheter so as to have the first guidewire replaced by the second guidewire.

Once the second guidewire is in position, the catheter is removed to leave the second guidewire in the desired position. Then, a preloaded guidewire, either carrying a stent or a stent-graft, may be inserted into the vessel along the guidewire already in the

- 2 -

vessel. This operation is carried out with the purpose of installing a stent or a graft in the site with the lesion.

5 The above operations may be extremely cumbersome when the blood vessel defines a tortuous path for the guidewires and catheters. When a guidewire or catheter must be advanced through a tortuous artery, a second guidewire, parallel to the first one, must be inserted into the blood vessel to make the vessel straight in order to facilitate the advancing of the pre-loaded guidewire. The advancing of the second guidewire, however, entails the same difficulties like the advancing of the first guidewire.

10 There is therefore need for a new and improved guidewire and/or catheter guiding system and method which can overcome these difficulties.

3. Summary of the Invention.

15 It is therefore one object of the present invention to provide a guiding device and method for inserting and advancing one or more than one catheter and/or guidewire through the vascular tree of a patient in endovascular treatments, particularly through tortuous blood vessels, the guiding device comprising an open or close guiding channel provided at a distal end of the catheter or guidewire, whereby the catheter or guidewire may be easily advanced through the vessel over a previously installed guidewire.

20 It is still another object of the present invention to provide a guiding device for inserting and advancing more than one catheter and/or guidewire through the vascular tree of a patient in endovascular treatments, the device comprising a catheter shaft comprising a proximal end, a distal end and at least one fluid delivery lumen in fluid communication with the proximal end and the distal end, the distal end including a wire-guiding channel or conduit for slidably receiving a guiding wire whereby the catheter may be advanced through a vessel of the patient by slidably advancing the distal end of the catheter over the 25 guiding wire.

30 It is a further object of the present invention to provide a guiding device for inserting and advancing one or more than one catheter and/or guidewire through the vascular tree of a patient in endovascular treatments, the device comprising a flexible conduit defining a main guidewire comprising a proximal end, a distal end and at least one lumen in fluid communication with the proximal end and the distal end, the distal end

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including a guiding channel for slidably receiving an additional guidewire whereby the main guidewire may be advanced through a vessel of the patient by slidably advancing the distal end over the additional guidewire.

It is even another object of the present invention to provide a guiding device for 5 inserting and advancing one or more than one catheter and/or guidewire through the vascular tree of a patient in endovascular treatments, the device comprising a metal guidewire with a distal end and a proximal end, the distal end including a guiding channel for slidably receiving an additional guidewire whereby the metal guidewire may be advanced through a vessel of the patient by slidably advancing the distal end over the 10 additional guidewire.

It is still another object of the present invention to provide a method for inserting and advancing one or more than one catheter and/or guidewire through the vascular system of a patient in endovascular treatments, the method comprising the steps of:

providing a catheter having a catheter shaft comprising a proximal end, a distal 15 end and at least one fluid delivery lumen in fluid communication with the proximal end and the distal end, the distal end including a guiding channel for slidably receiving a guiding wire,

inserting the guiding wire into the channel of the catheter, and
advancing the catheter through a vessel of the patient by slidably advancing the 20 distal end over the guiding wire.

It is even another object of the present invention to provide a method for inserting and advancing one or more than one catheter and/or guidewire through the vascular system of a patient in endovascular treatments, the method comprising the steps of:

providing a flexible conduit defining a guidewire comprising a proximal end, a 25 distal end and at least one lumen in fluid communication with the proximal end and the distal end, the distal end including a guiding channel for slidably receiving a guiding wire,

inserting the guiding wire into the channel of the flexible conduit, and
advancing the flexible conduit through a vessel of the patient by slidably advancing the distal end over the guiding wire.

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It is even another object of the present invention to provide a method for inserting and advancing one or more than one catheter and/or guidewire through the vascular tree of a patient in endovascular treatments, the method comprising the steps of:

5 providing a flexible metal guidewire comprising a proximal end and a distal end, the distal end including a guiding channel for slidably receiving an additional guidewire,

inserting the additional guidewire into the guiding channel of the flexible metal guidewire, and

advancing the metal guidewire through a vessel of the patient by slidably advancing the distal end over the additional guidewire.

10 The above and other objects, features and advantages of this invention will be better understood when taken in connection with the accompanying drawings and description.

BRIEF DESCRIPTION OF THE DRAWINGS

15 The present invention is illustrated by way of example in the following drawings wherein:

FIG. 1 shows a cross-sectional view of a blood vessel through which a catheter or a guidewire must be passed, the vessel having a tortuous path;

20 FIG. 2 shows a cross-sectional view of the blood vessel of Fig. 1, partially straightened by a guidewire inserted therein, with a second guidewire including the guiding system of the present invention and ready to be inserted into the vessel over the first, previously inserted guidewire;

25 FIG. 3 shows a cross-sectional view of the blood vessel of Figs. 1 and 2, straightened as desired by two guidewires inserted into the vessel by using one of the guidewires provided with the guiding system of the invention;

FIG. 4 shows a perspective partial cross-sectional view of a distal end of a guidewire including the guiding system of the invention;

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FIG. 5 shows a perspective partial cross-sectional view of a distal end of a catheter including the guiding system of the invention;

FIG. 6 shows a side elevation partial cross-sectional view of a distal end of a "Jockey" type catheter including the guiding system of the invention;

5 FIG. 7 shows a perspective view of a distal end of the "Jockey" type catheter of Fig. 6 including the guiding system of the present invention and running over a guidewire previously inserted into a blood vessel (not illustrated);

FIG. 8 shows a perspective view of a distal end of a catheter or guidewire including guiding system according to another embodiment of the invention;

10 FIG. 9 shows a cross-sectional view taken along line IX-IX of Fig. 8;

FIG. 10 shows a perspective view of a distal end of the catheter or guidewire of Fig. 8, with a guidewire being laterally inserted into the guiding system of the invention; and

FIG. 11 shows a cross-sectional view taken along line XI-XI of Fig. 10;

15

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Now referring in detail to the drawings it may be seen from Figs. 1-3 a tortuous blood vessel, like an artery 1 that is in the path for a catheter or a guidewire that must be inserted through the artery to reach a remote site of the vascular tree of a patient having a 20 lesion to be treated by an endovascular process, for example. The object of the present invention is to provide a guiding system for a guidewire or a catheter that must be inserted into vessel 1 to facilitate the insertion of the catheter and/or guidewire by making the vessel straightened through the method sequences shown in Figs. 2, 3. As it is shown in Fig. 2, a guidewire 2 has been inserted through vessel 1 by any well known procedure and the vessel is partially straightened due to the wire remaining into the vessel. Even when the vessel is not so tortuous like in Fig. 1, the path necessary for advancing other 25 guidewires or catheters, for instance a preloaded guidewire with a stent or a stent graft, is not clear enough as desired. Therefore, the vessel must be further treated to make it straight enough to proceed with the endovascular process. Thus, another guidewire 3 is

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5 inserted into the vessel, parallel to the first inserted guidewire 2. Guidewire 3, however, must be carefully maneuvered and steered into the vessel preventing the vessel from being damaged. According to the invention, a distal end 4 of guidewire 3 is provided with guiding means comprising a short channel or conduit 5 arranged on the outer surface of the guidewire. Although a conduit has been illustrated, also a ring, a groove or any other guiding channel may be provided.

10 According to a method of the invention, channel 5 is slidably advanced over guidewire 2, as indicated by the arrow, in order to place guidewire 3 parallel to guidewire 2, as it is shown in Fig. 3, and have the vessel straightened enough for further endovascular techniques to be carried out in the patient.

15 Although reference has been made to a guidewire 5, a catheter can also be advanced over guidewire 2, as it will be seen later in connection to Figs. 4, 5. Fig. 4 shows in more detail distal end 4 of guidewire 3. The distal end includes a short guiding channel, preferably a conduit 5, arranged on outer surface 6 of the guidewire. Guidewire 3 is a metal solid wire, while guiding conduit defines a path for slidably receiving guidewire 2 shown in phantom lines.

20 Fig. 5 shows the guiding system of the invention, preferably conduit 5, provided in a distal end 4 of a catheter 8, including a lumen 9 for carrying fluids or other medical tools. Conduit 5 is also slidably carried over guidewire 2 shown in phantom lines. Conduit 5 preferably has a length of 2cm to 3 cm. Conduit 5 may be a close conduit or may be longitudinally and laterally open, for instance with a longitudinal groove (not shown) to facilitate a side insertion of the conduit over guidewire 2. A further embodiment showing a side open groove applied to a catheter will be described in detail later in connection to Figs. 8-10. The provision of such a groove makes it easier and faster to inset the guidewire into the guiding conduit

25

30 Figs. 6 and 7 show a catheter 10 having a curved distal end 11, also known as a "Jockey" type catheter, wherein the guiding means of the invention, also consisting of a guiding conduit 5 like the one illustrated in Figs. 2-5, is provided. Catheter 10 has a lumen 12 and conduit 5 defines a channel 13 for passing a guidewire indicated by the same reference number 2 like in the other Figures. When conduit 5 is not open at its

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sides, the conduit must be inserted over the guidewire at a proximal end (not shown) of the guidewire 2. Otherwise, if a lateral or side groove is provided in the conduit, the latter may be inserted by pressure at any section over the guidewire.

5 Figs. 8-11 show another embodiment of the invention wherein the guiding means are devised by means of a side groove for receiving the guidewire. A catheter 14 includes, at a distal end 15 thereof, the guiding means of the invention comprising a guiding channel defined by a short portion 16 of the lumen of the catheter with openings 17, 18 at respective ends of the channel portion. Thus, guiding channel 16 is open to one side of the catheter, forming a resilient groove 19 capable of receiving guiding wire 2 and resiliently retaining the guiding wire within lumen 16. As shown, groove 19 is in fluid 10 communication with the lumen of the catheter and defines an entrance for the guidewire, the entrance being tangentially extended relative to an outer surface of the catheter.

15 Groove 19 provides at least one wide opening to the outside of the catheter or guidewire and becomes narrower as it comes into lumen 16 thus providing a safe retention of guidewire 2 within lumen 16, also thank to the resilient shape memory of these catheters and guidewires. Guidewire 2 must be inserted laterally to the catheter as indicated by arrow 20 in Figs. 10 and 11, by applying a predetermined pressure in order to allow the guidewire to reach the main lumen of the catheter or the guidewire. Thus a groove may be provided either in a catheter or in a guidewire with a lumen like lumen 16.

20 The above method, however, may have a drawback. If two independent elements, such as a guidewire and a catheter or two guidewires, trespass the valve of the introducer usually used in endovascular procedures, a blood leakage is very often generated through said valve. The solution to this potential cumbersome situation is to use a "Y" adapter advancing the two independent elements through each one of the adapter branches and 25 then producing the liaison of the two independents elements before passing the valve of the introducer.

30 Also according to the invention, a method for inserting and advancing more than one catheter and/or guidewire through the vascular tree of a patient, is provided, preferably in endovascular processes. The method may be carried out with a guidewire and a catheter or with two guidewires.

When a catheter (or guidewire) must be inserted into blood vessel 1, in addition to a previously inserted guidewire, the method comprises the steps of providing catheter 8 (or guidewire 3) having a catheter shaft comprising a proximal end, distal end 4 and at least one fluid delivery lumen 9, 12 in fluid communication with the proximal end and the distal end, the distal end including a guiding channel 5 for slidably receiving guiding wire 2, inserting the guiding wire into the channel of the catheter, and advancing the catheter through vessel 1 of the patient by slidably advancing the distal end over the guiding wire.

Once a guidewire has been inserted into vessel 1, another guidewire including the guiding means of the invention may be inserted according to the method of the invention.

When the guiding channel of the invention is provided with a side groove 19, the guiding channel does not need to be inserted over guidewire 2, at a proximal end of the guidewire, but guidewire may be inserted into the guide channel, as shown in Fig. 11, at any section of the guidewire, close to the patient's body.

When reference is made to "open" or "closed" guiding channel or conduit in this specification, it means that the guiding channel or conduit is open at its ends to receive a guidewire but the side walls of the conduit or channel may be open to allow the guidewire to be sideway inserted by pressure into the conduit or channel.

While preferred embodiments of the present invention have been illustrated and described, it will be obvious to those skilled in the art that various changes and modifications may be made therein without departing from the scope of the invention as defined in the appended claims.

I CLAIM:

1 1. Guiding device for inserting and advancing more than one catheter and/or
2 guidewire through the vascular tree of a patient in endovascular treatments, the device
3 comprising:

4 a catheter shaft comprising a proximal end, a distal end and at least one fluid
5 delivery lumen in fluid communication with the proximal end and the distal end,

6 the distal end including a wire-guiding channel for slidably receiving a guiding
7 wire whereby the catheter may be advanced through a blood vessel of the patient by
8 slidably advancing the distal end of the catheter over the guiding wire.

1 2. The guiding device of claim 1, wherein the guiding channel is a
2 longitudinal conduit.

1 3. The guiding device of claim 2, wherein the guiding channel is a short
2 portion of the lumen of the catheter, the short portion including openings at respective
3 ends thereof.

1 4. The guiding device of claim 1, wherein the guiding channel is open to one
2 side of the catheter, forming a resilient groove capable of receiving a guiding wire and
3 resiliently retaining the guiding wire therein.

1 5. The guiding device of claim 4, wherein the groove is in fluid
2 communication with the lumen of the catheter and defines an entrance for the guiding wire
3 that is tangentially extended relative to an outer surface of the catheter.

1 6. The guiding device of claim 1, wherein the guiding channel is a conduit
2 length arranged on an outer surface of the catheter.

1 7. The guiding device of claim 1, wherein the length of the channel is 2-3cm.

1 8. Guiding device for inserting and advancing more than one guidewire
2 through the vascular tree of a patient in endovascular treatments, the device comprising:

3 a flexible conduit defining a main guidewire comprising a proximal end, a distal
4 end and at least one lumen in fluid communication with the proximal end and the distal
5 end,

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6 the distal end including a guiding channel for slidably receiving an additional
7 guidewire whereby the main guidewire may be advanced through a blood vessel of the
8 patient by slidably advancing the distal end over the additional guidewire.

1 9. The guiding device of claim 8, wherein the main guidewire is a metal
2 guidewire with the channel being a side channel fixed to an outer surface of the wire.

1 10. The guiding device of claim 8, wherein the guiding channel is a
2 longitudinal conduit.

1 11. The guiding device of claim 10, wherein the guiding channel is a short
2 portion of the lumen of the flexible conduit with openings at respective ends of the short
3 portion.

1 12. The guiding device of claim 8, wherein the guiding channel is open to one
2 side of the flexible conduit, forming a resilient groove capable of receiving the additional
3 guidewire and resiliently retaining the additional guidewire therein.

1 13. The guiding device of claim 8, wherein the guiding channel is a conduit
2 length arranged on an outer surface of the flexible conduit.

1 14. The guiding device of claim 8, wherein the length of the channel is 2-3cm.

1 15. Guiding device for inserting and advancing more than one guidewire
2 through the vascular tree of a patient in endovascular treatments, the device comprising:

3 a metal guidewire with a distal end and a proximal end,

4 the distal end including a guiding channel for slidably receiving an additional
5 guidewire whereby the metal guidewire may be advanced through a blood vessel of the
6 patient by slidably advancing the distal end over the additional guidewire.

1 16. The guiding device of claim 15, wherein the guiding channel is a conduit
2 length arranged on an outer surface of the metal guidewire.

1 17. A method for inserting and advancing more than one catheter and/or
2 guidewire through the vascular system of a patient in endovascular treatments, the method
3 comprising the steps of:

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4 providing a catheter having a catheter shaft comprising a proximal end, a distal
5 end and at least one fluid delivery lumen in fluid communication with the proximal end
6 and the distal end, the distal end including a guiding channel for slidably receiving a
7 guiding wire,

8 inserting the guiding wire into the channel of the catheter, and

9 advancing the catheter through a vessel of the patient by slidably advancing the
10 distal end over the guiding wire.

1 18. The method of claim 15, wherein the channel is open to a side of the
2 catheter and the guidewire is sideways inserted into the guide channel.

1 19. A method for inserting and advancing more than one catheter and/or
2 guidewire through the vascular system of a patient in endovascular treatments, the method
3 comprising the steps of:

4 providing a flexible conduit defining a guidewire comprising a proximal end, a
5 distal end and at least one lumen in fluid communication with the proximal end and the
6 distal end, the distal end including a guiding channel for slidably receiving a guiding wire,

7 inserting the guiding wire into the channel of the flexible conduit, and

8 advancing the flexible conduit through a vessel of the patient by slidably advancing
9 the distal end over the guiding wire.

1 20. A method for inserting and advancing more than one catheter and/or
2 guidewire through the vascular tree of a patient in endovascular treatments, the method
3 comprising the steps of:

4 providing a flexible metal guidewire comprising a proximal end and a distal end,
5 the distal end including a guiding channel for slidably receiving an additional guidewire,

6 inserting the additional guidewire into the guiding channel of the flexible metal
7 guidewire, and

8 advancing the metal guidewire through a vessel of the patient by slidably
9 advancing the distal end over the additional guidewire.

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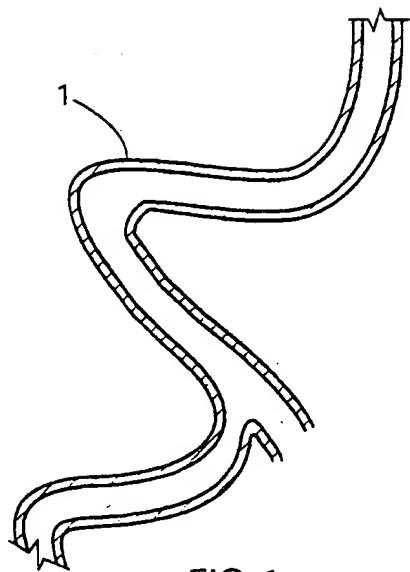


FIG. 1

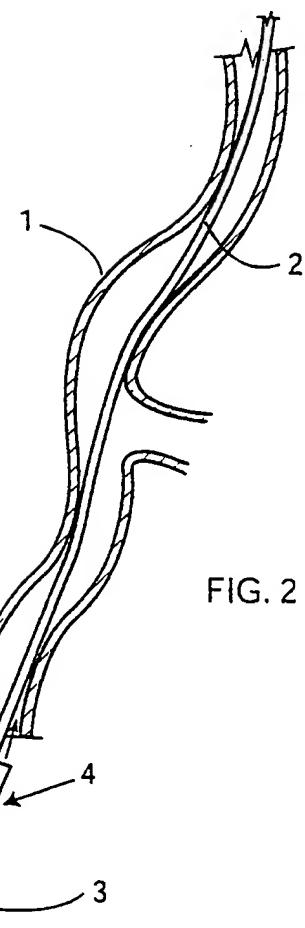


FIG. 2

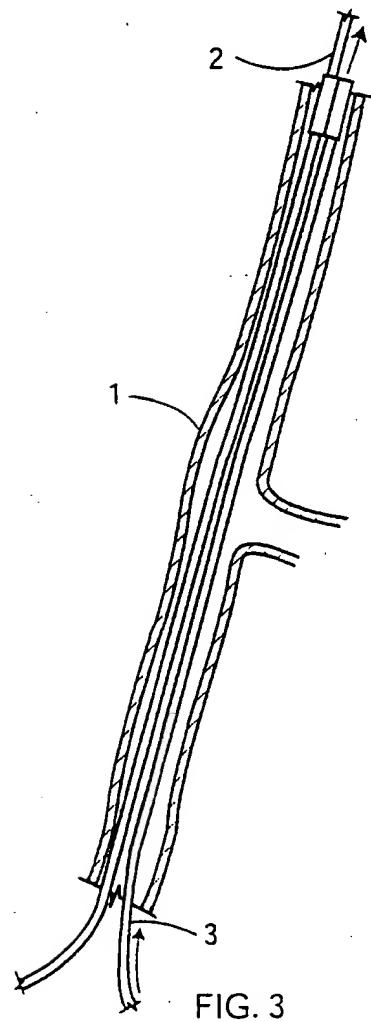


FIG. 3

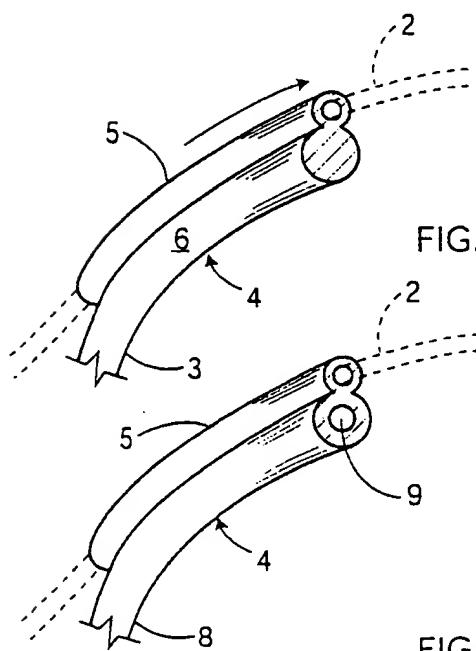


FIG. 4

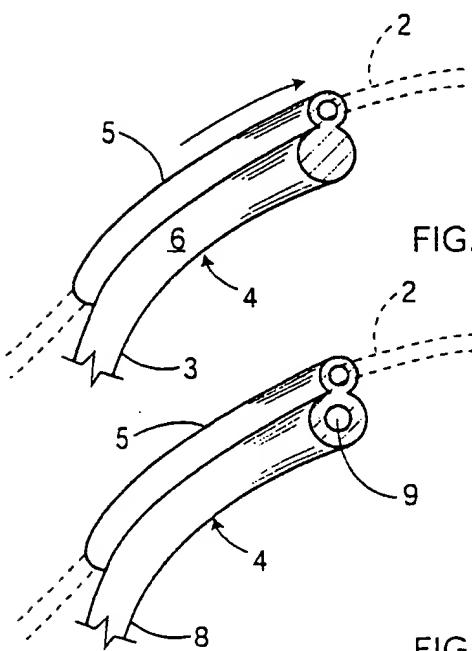


FIG. 5

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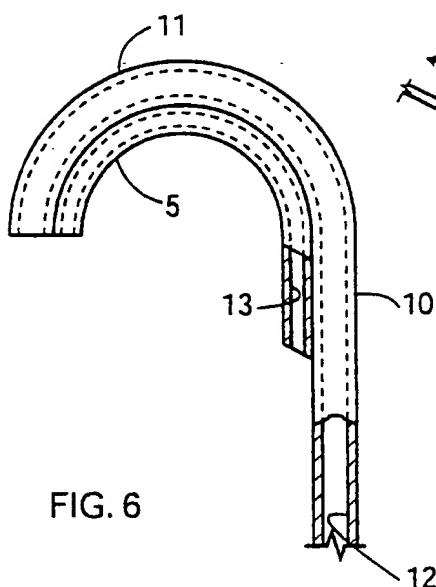


FIG. 6

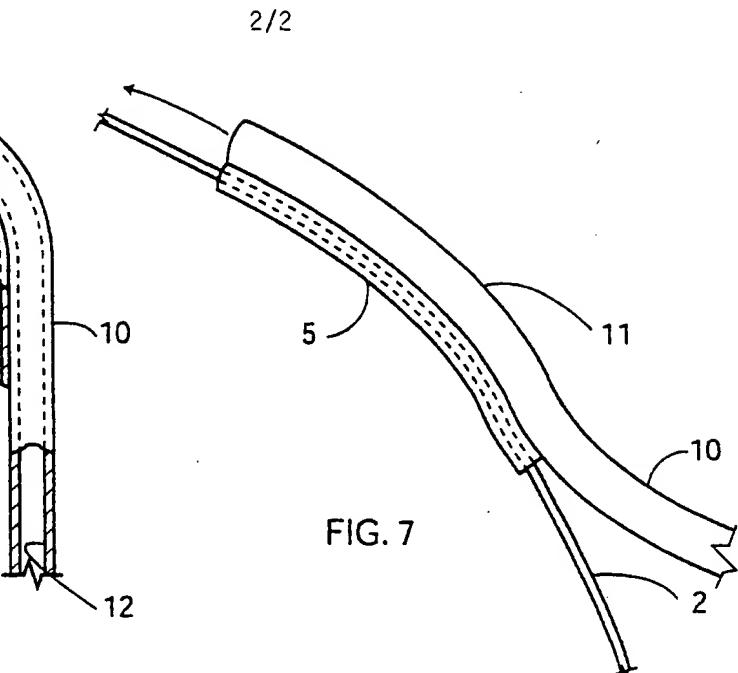


FIG. 7

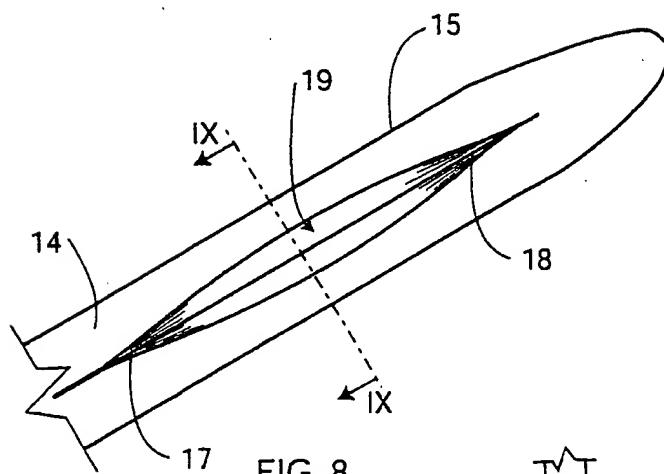


FIG. 8

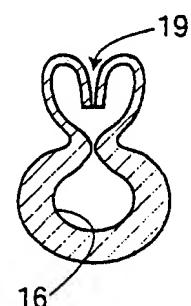


FIG. 9

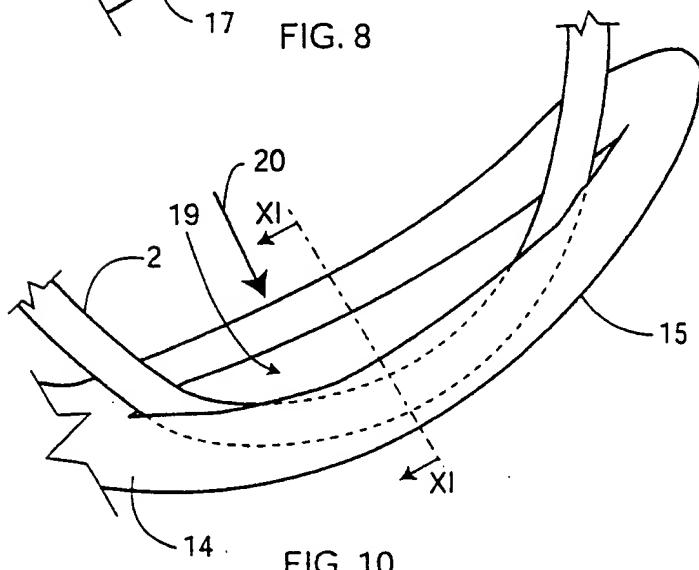


FIG. 10

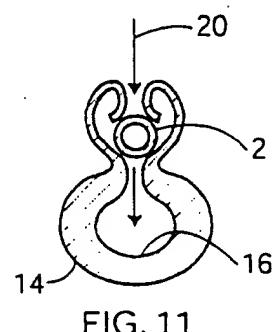


FIG. 11

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 99/01434

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 413 560 A (SOLAR RONALD J) 9 May 1995 (1995-05-09) column 3, line 41 -column 4, line 42; figures ---	1-3,6, 8-11,13, 15,16
X	US 5 388 590 A (HORRIGAN JOHN B. ET AL) 14 February 1995 (1995-02-14) column 4, line 15 -column 5, line 38; figures ---	1-3,6,8, 10,11, 13,15,16
A	US 5 024 234 A (LEARY) 18 June 1991 (1991-06-18) column 7, line 51 -column 8, line 6; figures --- -/-	1-4,6, 8-13,15, 16

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

11 October 1999

Date of mailing of the International search report

19/10/1999

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Kousouretas, I

INTERNATIONAL SEARCH REPORT

Intern	nal Application No
PCT/IB 99/01434	

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 449 362 A (CHAISSON GARY A ET AL) 12 September 1995 (1995-09-12) the whole document ----	1-4,6,8, 10-13,15
A	US 4 824 435 A (HOSKINS MATTHEW W ET AL) 25 April 1989 (1989-04-25) the whole document ----	1,8,15
A	US 5 040 548 A (YOCK PAUL G) 20 August 1991 (1991-08-20) column 7, line 55 -column 8, line 19; figures -----	1-3,6, 8-11

INTERNATIONAL SEARCH REPORT

Int. application No.
PCT/IB 99/01434

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 17-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat'l Application No

PCT/1B 99/01434

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